### REISSUE PATENT APPLICATION

I hereby certify that this caper is being deposited with the United States Postal Service was sufficient postage as Express Mail "Post Office to service, having mailing label number EL847395679US in an envelope addressed to: Box Reissue, Commissioner for Patents, Washington, D.C. 20231, on the date indicated below.

Stacy E. Jenkins. Paralegal

June 27, 2001

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

GEORGE R. SCHWARTZ

Serial No.:

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Filed:

Herewith

Patent No.:

5,916,242

Issued:

June 29, 1999

For:

APPARATUS FOR RAPID COOLING OF

THE BRAIN AND METHOD OF

PREFORMING SAME

Examiner: Unknown

Group Art Unit: 1911

# REISSUE APPLICATION PRELIMINARY AMENDMENT

BOX REISSUE Commissioner for Patents Washington, D.C. 20231

Dear Sir:

In the above-referenced newly filed Reissue Patent Application, please amend the patent as follows:

Please cancel claims 4 and 5.

Please add new claims 6-16:

- 6. An apparatus for inducing hypothermia in a patient's brain, comprising:
- a) a first coolant contact having inlet and outlet coolant conducting elements, the first coolant contact being insertable into the patient's oral cavity, whereby the first coolant contact contacts at least a portion of the surface of the oral cavity of the patient at a location where the oral cavity contains blood vessels and tissues proximate thereto;
- b) a second coolant contact having inlet and outlet coolant conducting elements, the second coolant contact being positionable around at least a portion of the patient's neck, whereby the second coolant contact contacts the exterior skin surface of the neck of the patient proximate the carotid artery; and
- c) a source of liquid or gaseous coolant in fluidic contact with the inlet and outlet coolant conducting elements of the first coolant contact and the second coolant contact, whereby the coolant from the coolant source flows through the inlet and outlet coolant conducting elements of the first coolant contact and the second coolant contact, cooling the first coolant contact and the second coolant contact and second coolant contact lower the temperature of the blood vessels and tissues proximately thereto contained in the oral cavity and the carotid artery, said tissues, blood vessels and carotid artery further acting as heat conducting paths from the brain to the first coolant contact and second coolant contact, whereby the temperature of the brain is lowered.
  - 7. The apparatus of claim 6 wherein the first coolant contact comprises a bladder.
  - 8. The apparatus of claim 6 wherein the second coolant contact comprises a collar.
- 9. The apparatus of claim 6 wherein the first coolant contact having inlet and outlet coolant conducting elements and the second coolant contact having inlet and outlet coolant

conducting elements comprise non-metallic fabric or plastic materials, whereby said apparatus is compatible with X-ray, MRI or CAT scan procedures.

- 10. A method of inducing hypothermia in a patient's brain, comprising the steps of:
- a) contacting at least a portion of the surface of the oral cavity of the patient at a location where the oral cavity contains blood vessels with a first coolant contact; and
- b) contacting the exterior skin surface of the neck of the patient proximate the carotid artery with a second coolant contact;

whereby the blood vessels and carotid artery are lowered in temperature to cool the brain.

- 11. The method of claim 10, further comprising the steps of:
- a) flowing coolant through the first coolant contact by means of an inlet tube to the first coolant contact and an outlet tube to the first coolant contact; and
- b) flowing coolant through the second coolant contact by means of an inlet tube to the second coolant contact and an outlet tube to the second coolant contact.
- 12. The method of claim 11 wherein there is a common source for the flowing coolant for the first coolant contact and the flowing coolant for the second coolant contact.
  - 13. The method of claim 10 wherein the first coolant contact comprises a bladder.
  - 14. The method of claim 10 wherein the second coolant contact comprises a collar.

- 15. A method of inducing hypothermia in a patient's brain, comprising the steps of:
- a) inserting a coolant contact comprising a bladder, an inlet coolant conducting tube and an outlet coolant conducting tube into the oral cavity of the patient, the bladder being in contact with tissues proximate blood vessels located at the rear of the patient's oral cavity; and
- b) flowing coolant through the bladder by means of the inlet coolant conducting tube and the outlet coolant conducting tube, whereby the tissues and blood vessels are lowered in temperature to cool the brain.
- 16. The method of claim 15 wherein the bladder is a toroidal bladder and the coolant contact further comprises an endotracheal tube, wherein the toroidal bladder surrounds the endotracheal tube.

#### **REMARKS**

This is a reissue application, wherein the Applicant seeks to add claims as set forth above.

Support for the new claims is found throughout the application, including specifically at col. 2, line 66 bridging col. 3, line 5, and at Figs. 1 to 4 of U.S. Patent 5,916,242.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached paper is captioned "<u>Version with Markings to Show Changes Made</u>."

Should the Examiner have any comments, questions or suggestions relating to a speedy disposition of the application, he is invited to call the undersigned.

Respectfully submitted,

By:

Dated: June 27, 2001

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### Version with Markings to Show Changes Made

- 1. Apparatus for inducing hypothermia in a patient's brain, said apparatus comprising:
  - a) an endotracheal tube having a first end and second end,
- b) a toroidal shaped bladder surrounding said tube proximate said first end of said tube, said first end for insertion into said patient's trachea whereby said bladder contacts the tissues and blood vessels of said patient's oral cavity,
- c) a source of liquid or gaseous coolant, said source for providing coolant to said bladder,
- d) inlet and outlet coolant conducting elements connected to said toroidal shaped bladder, whereby said coolant from said source flowing through said inlet and outlet coolant conducting elements cools said bladder, further whereby when said first end of said endotracheal tube is inserted into said patient's trachea, said coolant flowing in said bladder lowers the temperature of said tissues and blood vessels of said patient's oral cavity in contact with said bladder, said tissues and blood vessels further acting as heat conducting paths from said brain to said bladder whereby the temperature of said brain is lowered.
- 2. The apparatus of claim 1 wherein said endotracheal tube and said bladder comprise non-metallic fabric or plastic materials, whereby said apparatus is compatible with X-ray, MRI or CAT scan procedures.
- 3. The apparatus of claim 1 further comprising refrigeration means supplying said coolant.

- [4. A method of inducing hypothermia in a patient's brain comprising the step of:
- a) Cooling said brain by lowering the temperature of the blood flowing in blood vessels located in said patient's oral cavity,
- b) inserting an endotracheal tube into contact with said patient's trachea, said endotracheal tube having a toroidial bladder surrounding said endotracheal tube, said bladder being in contact with blood vessels located at the rear of said patient's oral cavity,
- c) flowing coolant through said bladder by means of an inlet tube to said bladder and an outlet tube from said bladder, whereby said blood vessels are lowered in temperature to cool said brain.]
  - [5. The method of claim 4 further comprising the steps of:
- a) inserting an endotracheal tube into contact with said patient's trachea, said endotracheal tube having a toroidal bladder surrounding said endotracheal tube, said bladder being in contact with blood vessels located at the rear of said patient's oral cavity and
- b) flowing coolant through said bladder by means of an inlet tube to said bladder and an outlet tube from said bladder, whereby said blood vessels are lowered in temperature to cool said brain.]
- 6. An apparatus for inducing hypothermia in a patient's brain, comprising:

  a) a first coolant contact having inlet and outlet coolant conducting

  elements, the first coolant contact being insertable into the patient's oral cavity, whereby the

  first coolant contact contacts at least a portion of the surface of the oral cavity of the patient at a

  location where the oral cavity contains blood vessels and tissues proximate thereto;

  b) a second coolant contact having inlet and outlet coolant conducting

  elements, the second coolant contact being positionable around at least a portion of the

patient's neck, whereby the second coolant contact contacts the exterior skin surface of the
neck of the patient proximate the carotid artery; and
c) a source of liquid or gaseous coolant in fluidic contact with the inlet and
outlet coolant conducting elements of the first coolant contact and the second coolant contact,
whereby the coolant from the coolant source flows through the inlet and outlet coolant
conducting elements of the first coolant contact and the second coolant contact, cooling the first
coolant contact and the second coolant contact, and the first coolant contact and second
coolant contact lower the temperature of the blood vessels and tissues proximately thereto
contained in the oral cavity and the carotid artery, said tissues, blood vessels and carotid artery
further acting as heat conducting paths from the brain to the first coolant contact and second
coolant contact, whereby the temperature of the brain is lowered.
7. The apparatus of claim 6 wherein the first coolant contact comprises a bladder.
8. The apparatus of claim 6 wherein the second coolant contact comprises a collar.
9. The apparatus of claim 6 wherein the first coolant contact having inlet and outlet
coolant conducting elements and the second coolant contact having inlet and outlet coolant
conducting elements comprise non-metallic fabric or plastic materials, whereby said apparatus
is compatible with X-ray, MRI or CAT scan procedures.
10. A method of inducing hypothermia in a patient's brain, comprising the steps of:
a) contacting at least a portion of the surface of the oral cavity of the patient
at a location where the oral cavity contains blood vessels with a first coolant contact; and
b) contacting the exterior skin surface of the neck of the patient proximate

the carotid artery with a second coolant contact;
whereby the blood vessels and carotid artery are lowered in temperature
to cool the brain.
11. The method of claim 10, further comprising the steps of:
a) flowing coolant through the first coolant contact by means of an inlet tube to
the first coolant contact and an outlet tube to the first coolant contact; and
b) flowing coolant through the second coolant contact by means of an inlet tube
to the second coolant contact and an outlet tube to the second coolant contact.
12. The method of claim 11 wherein there is a common source for the flowing
coolant for the first coolant contact and the flowing coolant for the second coolant contact.
13. The method of claim 10 wherein the first coolant contact comprises a bladder.
14. The method of claim 10 wherein the second coolant contact comprises a collar.
15. A method of inducing hypothermia in a patient's brain, comprising the steps of:
a) inserting a coolant contact comprising a bladder, an inlet coolant
conducting tube and an outlet coolant conducting tube into the oral cavity of the patient, the
bladder being in contact with tissues proximate blood vessels located at the rear of the patient's
oral cavity; and
b) flowing coolant through the bladder by means of the inlet coolant
conducting tube and the outlet coolant conducting tube, whereby the tissues and blood vessels
are lowered in temperature to cool the brain.

16. The method of claim 15 wherein the bladder is a toroidal bladder and the coolant contact further comprises an endotracheal tube, wherein the toroidal bladder surrounds the endotracheal tube.